

U.S. Patent Application Serial No. 10/538,912  
Amendment filed February 3, 2009  
Reply to OA dated September 5, 2008

**REMARKS**

Claims 1, 2 and 5-9 are pending in this application. Claims 2, 5, 6 and 8 are canceled without prejudice or disclaimer, and claims 1, 7 and 9 are amended herein. Upon entry of this amendment, claims 1, 7 and 9 will be pending. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for the amendments to the claims is discussed below.

**The specification is objected to under 35 U.S.C. §112, first paragraph, as failing to provide an adequate written description of the invention. (Office action p. 2)**

**Claims 1, 2 and 5-9 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while possible of being enabling for the Trk49 and Trk62 antibodies, does not reasonably provide enablement for the scope of antibodies as claimed or even for other antibodies specific for the 5a and 5b isoforms of tartrate resistant acid phosphatase. (Office action p. 2)**

The rejection is moot for claims 2, 5, 6 and 8, which are canceled without prejudice or disclaimer. The rejection of claims 1, 7 and 9 is overcome by the amendments to the claims. In the amendments to claims 1 and 9, the first antibody is limited to Trk62 and the second antibody is limited to Trk49. This amendment is supported by the general disclosure in the specification of the

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Trk49 and Trk62 antibodies and the evidence that these antibodies meet the limitations of the original claims and may be used in the method of the invention.

**Claims 1, 2 and 5-9 are further rejected under 35 U.S.C. §112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure. (Office action p. 2)**

At page 4, line 15, the Examiner states that:

"a deposit in an acceptable International Depository does not indicate that the deposit was made under the terms of the Budapest treaty and does not certify that the deposit meets the criteria set forth in 37CFR 1.801-1.809. Applicants have not shown that viable cell lines were deposited under the terms of the Budapest Treaty."

Applicant notes in this regard that 37 CFR 1.803(a) states that:

"(a) A deposit shall be recognized for the purposes of these regulations if made in

(1) Any International Depository Authority (IDA) as established under the Budapest Treaty

....., or

(2) Any other depository recognized to be suitable by the Office. ...."

Applicant here attaches Receipts in the Case of an Original Deposit under the Budapest Treaty for the subject hybridomas, demonstrating that the deposits at issue were made in an IDA under the Budapest treaty. Applicant has further attached statements verifying that these deposits were made under conditions that comply with 37 CFR 1.806 and 37 CFR 1.808(a). Reconsideration of the rejection is respectfully requested.

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**Claims 2 and 5-8 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office action p. 5)**

The Examiner again states that the preamble of the dependent claims should be amended "The [[An]] immunoassay method according to claim ...."

The rejection is moot for claims 2, 5, 6 and 8, which are canceled herein without prejudice or disclaimer. The rejection of claim 7 is overcome by the amendment to claim 7, amending the article "An" to --The--.

**Claim 9 is rejected under 35 U.S.C. §102(b) as being clearly anticipated by Furie et al. (U.S. 4,769,320) for reasons of record. (Office action p. 6)**

Reconsideration of the rejection is respectfully requested in view of the amendment to claim 9. Claim 9 has been amended to limit the first antibody to Trk62 and the second antibody to Trk49.

Applicant submits that Furie et al. does not disclose the Trk62 or Trk49 antibody.

**Claim 9 is rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Davalian et al. (U.S. 6,190,873) for reasons of record in the prior rejection of the similar subject matter of this claim. (Office action p. 7)**

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Reconsideration of the rejection is respectfully requested in view of the amendment to claim

9. Claim 9 has been amended to limit the first antibody to Trk62 and the second antibody to Trk49.

Applicant submits that Davalian et al. does not disclose the Trk62 or Trk49 antibody.

**Claims 1, 2 and 6-9 are rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Halleen et al. et al. (U.S. 6,248,544) for reasons of record in the prior rejection of the similar subject matter of these claims. (Office action p. 7)**

**Claims 1, 2 and 6-9 are under 35 U.S.C. §103(a) as being unpatentable over Halleen et al. (U.S. 6,248,544) in view of Carlsson et al. (U.S. 6,737,278) for reasons of record in the prior rejection of the similar subject matter of these claims. (Office action p. 7)**

The rejection is moot for claims 2, 5, 6 and 8, which are canceled without prejudice or disclaimer. The rejection of claims 1, 7 and 9 is overcome by the amendments to the claims.

Claim 1 has been amended to limit the first antibody to Trk62 and the second antibody to Trk49. In addition, claim 1 has been amended to incorporate the limitation of claim 6, limiting the target substance to tartrate resistant acid phosphatase 5b (TRACP 5b).

Claim 9 has been amended to limit the first antibody to Trk62 and the second antibody to Trk49.

Applicant submits that neither Halleen et al. nor Carlsson et al. discloses the Trk62 or Trk49 antibody.

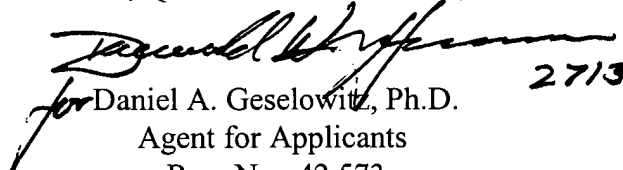
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If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants' undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

KRATZ, QUINTOS & HANSON, LLP

  
for Daniel A. Geselowitz, Ph.D. 27133  
Agent for Applicants  
Reg. No. 42,573

DAG/xl

Atty. Docket No. 050381  
Suite 400  
1420 K Street, N.W.  
Washington, D.C. 20005  
(202) 659-2930



23850

PATENT & TRADEMARK OFFICE

Enclosures: (1) RCE Transmittal  
(2) Petition for Extension of Time  
(3) Receipt in the Case of Original Deposit under the Budapest Treaty for Trk49 hybridoma  
(4) Receipt in the Case of Original Deposit under the Budapest Treaty for Trk62 hybridoma  
(5) Statement verifying nature of Original Deposits

H:\050\050381\Amendment Accompanying RCE in re FOA of 09-05-08



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of: **OHASHI, Tatsuya, et al.**

Group Art Unit: **1641**

Serial No.: **10/538,912**

Examiner: **GRUN, James Leslie**

Filed: **June 13, 2005**

P.T.O. Confirmation No.: **9528**

For: **IMMUNOASSAY METHOD AND KIT TO BE USED THEREIN**

**STATEMENT UNDER 37 C.F.R. § 1.808 (a)**

**MAILSTOP RCE**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

I, Katsuhiko KATAYAMA, do hereby declare that:

I am a co-inventor of the claimed inventions of the present application.

I am an executive officer of the medical division of Nitto Boseki Co., Ltd., the assignee of the present application.

I certify that the hybridomas Trk49 and Trk62 will be irrevocably and without restrictions or condition released to the public upon the issuance of a patent maturing from the present application, and the hybridomas will be replaced should they ever become non-viable.

Signed on this *29<sup>th</sup>* day of *Jan.*, 2009

*Katsuhiko Katayama*  
Katsuhiko KATAYAMA

Residence: Nitto Boseki Co., Ltd., 3-2-11 Kudan-Kita, Chiyoda-Ku, 102-0073 Tokyo, Japan

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF  
MICROORGANISMS FOR THE PURPOSES OF  
PATENT PROCEDURERECEIPT IN THE CASE OF AN ORIGINAL  
DEPOSIT

issued pursuant to Rule 7.1 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified at the bottom of this  
page.

特許手続上の微生物の寄託の国際的承認  
に関するブダペスト条約

下記国際寄託当局によって規則 7. 1 に従い  
発行される。

## 原寄託についての受託証

氏名 (名称)

日東紡績株式会社

代表者 相良 敦彦

寄託者

あ て 名 千

殿

福島県福島市郷野目字東 1 番地

## 1. 微生物の表示

(寄託者が付した識別のための表示)

TrK62

(受託番号)

FERM BP- 1890

## 2. 科学的性質及び分類学上の位置

1 棚の微生物には、次の事項を記載した文書が添付されていた。

- 科学的性質
- 分類学上の位置

## 3. 受領及び受託

本国際寄託当局は、平成 14 年 2 月 14 日 (原寄託日) に受領した 1 棚の微生物を受託する。

## 4. 移管請求の受領

本国際寄託当局は、 年 月 日 (原寄託日) に 1 棚の微生物を受領した。  
そして、 年 月 日 に原寄託よりブダペスト条約に基づく寄託への移管請求を受領した。

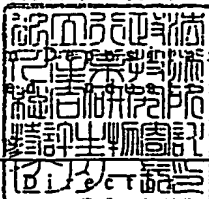
## 5. 国際寄託当局

独立行政法人産業技術総合研究所 特許生物寄託センター

International Patent Organisation  
名称: National Institute of Advanced Industrial Science and Technology

センター長 小松 泰

Dr. Yasuhiko Komatsu



あて名: 日本国茨城県つくば市東 1 丁目 1 番地 1 中央第 6 (郵便番号 305-8566)

AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi,  
Ibaraki-ken 305-8566 Japan

平成 14 年 (2002) 2 月 14 日

INTERNATIONLA FORM

Budapest Treaty on the International  
Recognition of the Deposit of  
Microorganisms for the Purposes of  
Patent Procedure

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF  
MICROORGANISMS FOR THE PURPOSES OF  
PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL  
DEPOSIT

Issued pursuant to Rule 7.1 by the  
International Depositary Authority  
as stated below

issued pursuant to Rule 7.1 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified at the bottom of this  
page.

Deposition Receipt for Original  
Deposition

Depositor

Name NITTO BOSEKI CO., LTD.  
President Atsuhiko SAGARA

Address of 1, Aza Higashi, Goonome, Fukushima-shi,  
Fukushima Prefecture

1. Indication of microorganism	
(Indication for identity provided by depositor) TrK62	(Accession number) FERM BP- 7890
2. Scientific properties and taxonomical position	
The following documents were attached to the microorganism of Column 1.	
<input checked="" type="checkbox"/> Scientific properties <input checked="" type="checkbox"/> Taxonomical position	
3. Receipt and acceptance	
The present International Depositary Authority accepted the microorganism of Column 1 which was received on February 14, 2002 (original deposition date)	
4. Receipt of demand for transfer	
5. International Depositary Authority	
Independent Administrative Juridical Person      Deposition Center for Patent Organism Industry Technology General Research	
Name: International Patent Organism Depositary National Institute of Advanced Industrial Science and Technology  Chief of Center: Yasuhiko Komatsu _____ Dr. Yasuhiko Komatsu, Director	
Address: Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki- ken 305-8566 Japan AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki-ken 305-8566 Japan	
February 14, 2002	



BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF  
MICROORGANISMS FOR THE PURPOSES OF  
PATENT PROCEDURE[ 特許手続上の微生物の寄託の国際的承認  
に関するブタベスト条約 ]下記国際寄託当局によって規則10.2に従い  
発行される。

## VIABILITY STATEMENT

issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following page.

## 生存に関する証明書

氏名 (名称)

日東紡績株式会社  
代表者 相良 敦彦

申請者

あて名 〒

福島県福島市郷野目字東1番地

殿

1. 寄託者		2. 微生物の表示	
氏名 (名称)	日東紡績株式会社 代表者 相良 敦彦	受託番号:	
あて名 〒	福島県福島市郷野目字東1番地	FERM BP- 7890	
		受託の日:	
		平成 14 年 2 月 14 日	
3. 生存試験の結果			
2 欄の微生物の生存について 平成 14 年 3 月 7 日に試験を実施した結果、当該微生物は、			
<input checked="" type="checkbox"/> 生存していた。			
<input type="checkbox"/> 生存していなかった。			
4. 生存試験に際して使用した条件 (結果が否定的である場合のみ)			
<input type="checkbox"/> 微生物条件記録書の写し 1 通			
5. 国際寄託当局			
独立行政法人産業技術総合研究所 特許生物寄託センター			
International Patent Organism Depositary			
名称: National Institute of Advanced Industrial Science and Technology			
センター長 小松 泰彦			
あて名: 日本国茨城県つくば市東1丁目1番地1 中央第6 (郵便番号 305-8566)			
AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki-ken 305-8566 Japan			
平成14年(2002) 3月 8日			

INTERNATIONLA FORM

Budapest Treaty on the International  
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Patent Procedure

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF  
MICROORGANISMS FOR THE PURPOSES OF  
PATENT PROCEDURE

VIABILITY STATEMENT

Issued pursuant to Rule 10.2 by the  
International Depositary Authority  
as stated below

issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following this  
page.

Viability Certificate

Demander

Name NITTO BOSEKI CO., LTD.  
President Atsuhiko SAGARA

Address of 1, Aza Higashi, Goonome, Fukushima-shi,  
Fukushima Prefecture

1. Depositor		2. Identification of Microorganism	
Name	NITTO BOSEKI CO., LTD. President Atsuhiko SAGARA	Accession number:	FERM BP- 7890
Address	of 1, Aza Higashi, Goonome, Fukushima-shi, Fukushima Prefecture	Accession date:	February 14, 2002
3. Results of Viability Examination			
The viability examination for the microorganism of Column 2 was conducted on March 7, 2002, and as a result, the microorganism was <input checked="" type="checkbox"/> viable <input type="checkbox"/> not viable			
4. Conditions for Viability Examination (only when the result was negative)			
<input type="checkbox"/> Copy of Record of Conditions for Viability Examination      one			
5. International Depositary Authority			
Independent Administrative Juridical Person		Deposition Center for Patent Organism	
Industry Technology General Research			
Name:	International Patent Organism Depositary National Institute of Advanced Industrial Science and Technology		
	Chief of Center: Yasuhiko Komatsu		
	Dr. Yasuhiko Komatsu, Director		
Address:	Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki- ken 305-8566 Japan AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki-ken 305-8566 Japan		
	March 8, 2002		

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

特許手続上の微生物の寄託の国際的承認  
に関するブダペスト条約

下記国際寄託当局によって規則7.1に従い  
発行される。

# 原寄託についての受託証

氏名 (名称) 日東紡績株式会社  
代表者 相良 敦彦 殿  
寄託者 あて名 〒 福島県福島市郷野目字東1番地

1. 微生物の表示	
(寄託者が付した識別のための表示) TrK49	(受託番号) FERM BP- 8249
2. 科学的性質及び分類学上の位置	
1 欄の微生物には、次の事項を記載した文書が添付されていた。 <div style="display: flex; justify-content: space-around;"> <div>■ 科学的性質</div> <div>■ 分類学上の位置</div> </div>	
3. 受領及び受託	
本国際寄託当局は、平成14年11月27日(原寄託日)に受領した1 欄の微生物を受託する。	
4. 移管請求の受領	
本国際寄託当局は、 <div style="display: flex; justify-content: space-between;"> <div>年 月 日 (原寄託日) に1 欄の微生物を受領した。</div> <div>そして、年 月 日に原寄託よりブダペスト条約に基づく寄託への移管請求を受領した。</div> </div>	
5. 国際寄託当局	
<p>独立行政法人産業技術総合研究所 特許生物寄託センター</p> <p>International Patent Organism Depository</p> <p>名称: National Institute of Advanced Industrial Science and Technology</p> <p>センター長 岡 修</p> <p>Dr. Syuichi Oka, Director</p> <p>あて名: 日本国茨城県つくば市東1丁目1番地1 中央第6 (郵便番号 305-8566)</p> <p>AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki-ken 305-8566 Japan</p>	
平成14年(2002)11月27日	

Budapest Treaty on the International  
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Microorganisms for the Purposes of  
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BUDAPEST TREATY ON THE INTERNATIONAL  
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as stated below

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identified at the bottom of this  
page.

Deposition Receipt for Original  
Deposition

Depositor

Name NITTO BOSEKI CO., LTD.  
President Atsuhiko SAGARA

Address of 1, Aza Higashi, Goonome, Fukushima-shi,  
Fukushima Prefecture

1. Indication of microorganism	
(Indication for identity provided by depositor) TrK49	(Accession number) FERM BP- 8249
2. Scientific properties and taxonomical position	
The following documents were attached to the microorganism of Column 1.	
<input checked="" type="checkbox"/> Scientific properties <input checked="" type="checkbox"/> Taxonomical position	
3. Receipt and acceptance	
The present International Depositary Authority accepted the microorganism of Column 1 which was received on November 27, 2002 (original deposition date)	
4. Receipt of demand for transfer	
5. International Depositary Authority	
Independent Administrative Juridical Person      Deposition Center for Patent Organism	
Industry Technology General Research	
Name: International Patent Organism Depositary National Institute of Advanced Industrial Science and Technology	
Chief of Center: Syuichi Oka	
Dr. Syuichi Oka, Director	
Address: Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki- ken 305-8566 Japan AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki-ken 305-8566 Japan	
November 27, 2002	

特許手続上の微生物の寄託の国際的承認  
に関するブタベスト条約

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF  
MICROORGANISMS FOR THE PURPOSES OF  
PATENT PROCEDURE

下記国際寄託当局によって規則10.2に従い  
発行される。

VIABILITY STATEMENT

issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified at the bottom of this  
page.

生存に関する証明書

氏名 (名称) 日東紡績株式会社  
代表者 相良 敦彦  
申請者 殿  
あて名 〒 福島県福島市郷野目字東1番地

<p>1. 寄託者</p> <p>氏名 (名称) 日東紡績株式会社 代表者 相良 敦彦</p> <p>あて名 〒 福島県福島市郷野目字東1番地</p>	<p>2. 微生物の表示</p> <p>受託番号: FERM BP- 8249</p> <p>受託の日: 平成 14 年 11 月 27 日</p>
<p>3. 生存試験の結果</p> <p>2 欄の微生物の生存について 平成 14 年 12 月 18 日 に試験を実施した結果、当該微生物は、</p> <p><input checked="" type="checkbox"/> 生存していた。</p> <p><input type="checkbox"/> 生存していなかった。</p>	
<p>4. 生存試験に際して使用した条件 (結果が否定的である場合のみ)</p> <p><input type="checkbox"/> 微生物条件記録書の写し 1 通</p>	
<p>5. 国際寄託当局</p> <p>独立行政法人産業技術総合研究所 特許生物寄託センター</p> <p>International Patent Organism Depositary 名称: National Institute of Advanced Industrial Science and Technology</p> <p>センター長 岡 修一 Dr. Syuichi Oka, Director</p> <p>あて名: 日本国茨城県つくば市東1丁目1番地1 中央第6 (郵便番号305-8566) AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki-ken 305-8566 Japan</p> <p>平成14年 (2002) 12月19日</p>	

FORM 10 (Regarding Article 9)

Budapest Treaty on the International  
Recognition of the Deposit of  
Microorganisms for the Purposes of  
Patent Procedure

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF  
MICROORGANISMS FOR THE PURPOSES OF  
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VIABILITY STATEMENT

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page.

Viability Certificate

Demander

Name NITTO BOSEKI CO., LTD.  
President Atsuhiko SAGARA

Address of 1, Aza Higashi, Goonome, Fukushima-shi,  
Fukushima Prefecture

1. Depositor		2. Identification of Microorganism	
Name	NITTO BOSEKI CO., LTD. President Atsuhiko SAGARA	Accession number:	FERM BP- 8249
Address	of 1, Aza Higashi, Goonome, Fukushima-shi, Fukushima Prefecture	Accession date:	November 27, 2002
3. Results of Viability Examination			
The viability examination for the microorganism of Column 2 was conducted on December 18, 2002, and as a result, the microorganism was <input checked="" type="checkbox"/> viable <input type="checkbox"/> not viable			
4. Conditions for Viability Examination (only when the result was negative)			
<input type="checkbox"/> Copy of Record of Conditions for Viability Examination      one			
5. International Depositary Authority			
Independent Administrative Juridical Person		Deposition Center for Patent Organism	
Industry Technology General Research			
Name:	International Patent Organism Depositary National Institute of Advanced Industrial Science and Technology		
	Chief of Center: Syuichi Oka		
	Dr. Syuichi Oka, Director		
Address:	Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki- ken 305-8566 Japan AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki-ken 305-8566 Japan		
	December 19, 2002		